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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,862	08/19/2003	Michael J. Pugia	55197-00016USPT	5515
30223	7590	04/04/2005	EXAMINER	
JENKENS & GILCHRIST, P.C.			SOOHOO, TONY GLEN	
225 WEST WASHINGTON			ART UNIT	
SUITE 2600			PAPER NUMBER	
CHICAGO, IL 60606			1723	

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/643,862

**Applicant(s)**

PUGIA ET AL.

**Examiner**

Tony G. Soohoo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8-19-03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8-119-03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. Claims 4 and 6-20 provides for a description of the structural elements of a third chamber, and chambers or passageways having particular geometry, the claims, however, do not positively state a manipulation step further limiting the manipulation of the method claims which are directed to the flow of the fluid into a third channel, nor a provision of flow of fluid through of chambers of having the particular volumes or passageway lengths, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a structural element without any active, positive steps delimiting how this structure is used or is actually practiced.
2. Claims 25-28, and 29-30, and 36 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims 25-28 refer to 1<sup>st</sup> and 2<sup>nd</sup> containers, but does not provide proper antecedent basis for the containers. Furthermore, claims 25-28 refer to the volume or depth of fluid in comparison within the chamber to that of the containers, however since the volume of the containers can not be positively determined, the size of the chambers can not be determined. With regards to claims 29 and 30, the claims point out space in the chamber relative to a flow of fluid. Whereby the flow of fluid is a dependent upon manipulative operation with regards to the amount fed into the chamber, the space above the level of fluid in the chambers does not provide a positive patentable structural limitation whereby the level

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of fluid causing the space is directed to a method of operation and not to a structural feature in an apparatus claim. With regards to claim 36 the size of the passageway can not be positively determined whereby the flow velocity is dependent upon operational factors in the method of use, such as, viscosity of the fluid, the pressure, osmotic, or electrophoresis, effects placed upon material to urge the flow, and such operation within an apparatus claim is provided little patentable weight.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 20, and 21-24, are rejected under 35 U.S.C. 102(e) as being anticipated by Koop et al US 6457854 (cited on PTO 1449).

The Koop reference discloses an apparatus and method of use for mixing fluids including two inlets for a 1<sup>st</sup> and 2<sup>nd</sup> fluid to be fed into a 1<sup>st</sup> chamber at the intersection of 9,10, a second chamber through seventh at the intersection of the sinusoidal loops

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which are microchannel capillary passageways along the portion 8, see figure 1, which ends at an outlet chamber at 5 for further processing.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6-16, 18-19, 25-36, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koop et al US 6457854.

The Koop (et al) reference discloses all of the recited subject matter as defined within the scope of the claims with the exception of the structure and method of flowing fluid within the chambers having particular volumes, the amount of volume flow level and velocity in the chamber and passageway, the cross sectional dimension, lengths, and number of passageways between channels, and the use of wells as a manner to provide hold the 1<sup>st</sup> and 2<sup>nd</sup> liquids.

With regards to having particular volumes, the cross sectional dimension, lengths of the passageways and chambers, a person having ordinary skill in the art in fluid processing would recognize such a size change in geometry would be a direct variable in the production of the amount of fluid which may be processed, and the residence time of processing, accordingly, it is deemed that it would have been obvious to one of ordinary skill in the art to modify the volumes, the cross sectional dimension, lengths of the passageways and chambers so as to optimize the amount of fluid processed and

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the residence time of interaction, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With regards to the number of passageways between channels, absent any unexpected results with the addition of a 3<sup>rd</sup> or more channel, it is deemed that it would have been obvious to one of ordinary skill in the art to duplicate at least another channel so that a 3<sup>rd</sup> sinusoidal pathway is provide to produce additional mixing effect since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

With regards to the amount of level of fluid and velocity of fluid in the method claims, it is commonly known that the level of fluid in a chamber and velocity of fluid flow in a pathway is a direct effective variable in the amount of fluid processed, accordingly absent any unexpected result, it is deemed that it would have been obvious to one of ordinary skill in the art to modify flow velocity and the level of amount of fluid so that the level is of a spacing as recited in the claims so as to optimize the amount fluid that is processed.

With regards to the use of wells, as a manner to hold the 1<sup>st</sup> and 2<sup>nd</sup> fluids, the use of wells as a means to hold and supply fluid in microfluidic devices are old and well known, accordingly, it is deemed that it would have been obvious to one of ordinary skill in the art to substitute for the feed lines of the Koop (et al) reference with wells so as to better supply a small amount of fluid flow into the mixing device.

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6. Claims 5, 17, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koop et al US 6457854 as applied to claims 1 and 21 respectively above, and further in view of Jakajima et al 6281254.

The Koop (et al) reference discloses all of the recited subject matter as defined within the scope of the claims with the exception of feeding the fluid in the second chamber in the form of droplets, using ramps or steps to combine the liquids, and structure which prevents premature movement of the fluids.

The Jakajima (et al) reference discloses a mixing channel or chamber 3 having steps or ramp elements 2 which assist in providing a mixing of fluids from the inlet 16 through the inlet chamber 14 to produce droplets at the 2<sup>nd</sup> side of ramps in the form of droplets, see figure 1, and figure 4, 5, in a controlled movement of the fluids,

In view of the teaching of the Jakajima (et al) reference, it is deemed that it would have been obvious to one of ordinary skill in the art to provide for the chambers of the Koop (et al) reference with ramps which assist in providing a mixing of fluids to produce droplets at the 2<sup>nd</sup> side of ramps in the form of droplets in a controlled movement of the fluids so as to produce a more effective emulsion of the mixed fluid.

### ***Conclusion***

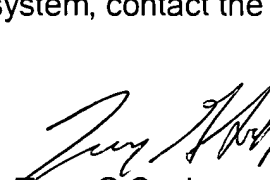
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Regnier et al 6170981 (cited on PTO 1449), Sundberg et al 6709559, Desai et al 5921678 (cited on PTO 1449), Manz et al 6540896, Ross et al 6254754, Parce et al 639974, McNeely et al 6296020, Parce et al 6238538, Nordman 6176991, Manz 5180480, Hillman et al 4963498.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tony G. Soohoo whose telephone number is (571) 272 1147. The examiner can normally be reached on 7:00 AM - 5:00 PM, Tues. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Tony G Soohoo  
Primary Examiner  
Art Unit 1723

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